FEB 1 5 2002

510(k) SUMMARY
Vascular Control Systems, Inc.
VCS-A Series Clamp with Ultrasound Doppler

K011863

1. GENERAL

- *Submitter:* Vascular Control Systems, Inc.
  32236-E Paseo Adelanto
  San Juan Capistrano, CA 92675
- *Contact Person:* Al Memmolo
  V.P. Quality and Regulatory Affairs
- *Date Prepared:* February 6, 2002

2. DEVICE NAME

- *Classification name:* Vascular Clamp (21 CFR §870.4450)
- *Common or usual name:* Vascular Clamp
- *Trade or proprietary name:* VCS-A Series Clamp with Ultrasound Doppler

3. PREDICATE DEVICES

- *510(k) #* *K973080*
- *Company:* *Walter Lorenz Surgical, Inc.*
- *Device Classification:* *Class II*
- *Device Name:* *Surgical Vascular Clamp*
- *Clearance Date:* *Feb 23, 1998*

- *510(k) #* *K935994*
- *Company:* *Koven Technologies, Inc.*
- *Device Classification:* *Class II*
- *Device Name:* *PW Doppler Vascular Probes*
- *Clearance Date:* *May 11, 1995*

4. DEVICE DESCRIPTION

The VCS-A Series Clamp with Ultrasound Doppler is a ring handled mechanical surgical instrument with a ratchet closure to adjust the tension required to occlude the target vessel. The clamp has an integrated Doppler probe, which allows for blood flow sensing by using a commercial available portable Doppler Ultrasound unit. The VCS-A Series clamp is manufactured from stainless steel and is available in various sizes and jaw configurations. The clamp is a sterile, single use device. The method of sterilization will be Gamma Radiation with a SAL of 10^{-6}.

510(k) Summary
VCS-A Series Vascular Clamp

5. INTENDED USE

The intended use is the temporary occlusion of blood vessels during vascular surgical procedures.

6. SUBSTANTIAL EQUIVALENCE

Vascular Control Systems, Inc. believes the VCS-A Series Clamp with Ultrasound Doppler raises no new questions of safety and efficacy based upon indications for use and device design. Therefore, we conclude that the VCS-A Series Clamp meets the requirements for substantial equivalence according to Section 510(k) guidelines.

7. PRODUCT PERFORMANCE TESTING

The performance and functional testing demonstrated that the vascular clamp is substantially equivalent to the predicate devices. The VCS-A series Clamp with Ultrasound Doppler does not raise any new safety, effectiveness, or performance issues. Data are on file at Vascular Control Systems, Inc.

8. CONCLUSIONS

Based on the same intended use, similar technological characteristics and performance testing, Vascular Control Systems, Inc. believes the VCS-A Series Clamp with Ultrasound Doppler is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 1 5 2002

Mr. Al Memmolo
Vice President of Quality Assurance
and Regulatory Affairs
Vascular Control Systems, Inc.
32236-E Paseo Adelanto
San Juan Capistrano, CA 92675

Re: K011863
Trade Name: VCS-A Series Clamp
Regulation Number: 21 CFR 870.4450
Regulation Name: Vascular Clamp
Regulation Number: 21 CFR 892.1570
Regulation Name: Diagnostic Ultrasound Transducer
Regulatory Class: II (two)
Product Code: 72 DXC and 90 ITX
Dated: February 6, 2002
Received: February 8, 2002

Dear Mr. Memmolo:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the Koven ES-100X, as described in your premarket notification:

Transducer Model Number

09-0005-01
09-0005-02
09-0005-03
09-0005-04

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This determination of substantial equivalence is granted on the condition that prior to shipping the first device, you submit a postclearance special report. This report should contain complete information, including acoustic output measurements based on production line devices, requested in Appendix G, (enclosed) of the Center's September 30, 1997 "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers." If the special report is incomplete or contains unacceptable values (e.g., acoustic output greater than approved levels), then the 510(k) clearance may not apply to the production units which as a result may be considered adulterated or misbranded.

The special report should reference the manufacturer's 510(k) number. It should be clearly and prominently marked "ADD-TO-FILE" and should be submitted in duplicate to:

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801, please contact the Office of Compliance at (301) 594-4591. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

If you have any questions regarding the content of this letter, please contact O.D. Hottenstein, Ph.D. at (301) 443-8262.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Acting Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosures

510(k) Number (if known): K011863

Device Name: VCS-A Series Clamp

Indications for Use:

The VCS-A Series Clamp is indicated for use in the temporary occlusion of blood vessels during vascular surgical procedures.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter-Use _____
(Per 21 CFR 801.109)

Division of Cardiovascular & Respiratory Devices
510(k) Number K011863